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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,572	08/14/2006	Heidi Lopez de Diego	453-US-PCT	6471

45821 7590 01/22/2009
LUNDBECK RESEARCH USA, INC.
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
PARAMUS, NJ 07652

EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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01/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,572	Applicant(s) DE DIEGO ET AL.	
	Examiner EMILY BERNHARDT	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47,48,50-54,56-59 and 61-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47,48,50-54,56-59 and 61-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

In view of applicants' response filed on 11/13/08 the following applies.

Claims 50-53 and 56-57 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In traversing the rejection that the claims in each set are not duplicates, there is no indication how claims 50 vs 51 vs 52 vs 53 materially differ in scope given that the specification teaches that the data recited in 51-53 is directed to the alpha form. The same remarks apply to 56 vs 57. Reciting additional properties for the same compound does not change the scope of compound unless there is a distinction such as differences in purity levels which the current specification does not point out. Thus the urged difference is still unclear.

Claim 64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Contrary to what applicants urge depression arising from bipolar disorder as recited in new claim 64 lacks descriptive support in the disclosure as originally filed. None of the pages pointed out describe this. What is described is treating "mania in bipolar disorder".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 47,48,50-54,56-59 and 61-63 and new claim 64 (directed to treating depression) remains rejected under 35 U.S.C. 103(a) as being unpatentable over Bogeso in view of EP and US Bogeso for reasons of record. Applicants' traverse is not persuasive for the following reasons. The unusually potent effects for racemic as well as resolved compound 38 would not teach away from employing other salt forms of 38 since the therapeutic activity is not taught to reside in the use of the particular salts but rather the thrust of the structure-activity results in Bogeso is the variation of substituents on the indan as well as piperazine ring. Thus a fair reading of the article would suggest that the salt forms are being employed as a form of delivery- i.e. more easily isolated as a crystalline form rather than the free base counterpart being obtained as residues as described in the experimental section. It is not believed that EP Bogeso is too diffuse to suggest the succinic salt forms because none of the examples were obtained in that form. It is well settled that a reference is not limited to its preferred embodiments or working examples but for all that it fairly teaches. See *In re Lamberti* 192 USPQ 278; *In re Mills* 176 USPQ 196; *In re Burckel* 201 USPQ 67 regarding the latter point. Additionally, contrary to what applicants state about US Bogeso the list of salts appearing in col.32 appear to be a preferred subset as they are of a much narrower scope than the list appearing in col. 2. Note also that succinic is mentioned in col.32. The recent Supreme Court decision (*KSR v. Teleflex* 82 USPQ2d 1385) is not seen to be contrary to the examiner's position. Note the following passage in the decision at p.1390:

“Third, the court erred in concluding that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try. When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” Applicants minimize the recent Pfizer decision because they urge it cannot overrule the older Papesch decision. However, it is believed that applicants’ reliance on *In re Papesch* is misplaced. While evidence of unexpected properties can overcome obviousness, the courts have repeatedly rejected the requirement that the prior art must also suggest the property being relied on by applicants. Note for example, *In re Mayne* 41 USPQ2d 1451.

Applicants’ reliance on the comparative showing remains unpersuasive for reasons set forth in the previous action. While many of the dependent claims are limited to the 1:1 salt, main claim 47 and 58-64 are not. This aside, in 2 of the 3 tests reported in the specification the malonic acid salt tested less favorably than the prior art fumarate salt. Additional deficiencies were pointed out in the previous action.

Note *Ex parte Gelles* 22 USPQ 2d 1318 (at 1319): “The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter “as a class” relative to the prior art subject matter.” . Additionally, differences in test results should be clearly shown as unexpected, and of both statistical and practical significance as was also stressed in *Gelles*.

The IDS of 2/21/08 is being forwarded to applicants. Some of the entries are duplicates of those cited in other IDS statements, and have been crossed out. Cox is still not seen in the file. Applicants point to a copending case as having this reference but it is not readily seen. Note that MPEP 609 requires applicants to point out the pertinent pages. If such is not indicated the reference will not be considered.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is 571-272-0664.

If attempts to reach the examiner by telephone are unsuccessful, the acting supervisor for AU 1624, James O. Wilson can be reached at 571-

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272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Bernhardt/
Primary Examiner, Art Unit
1624

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